

Atty Dkt. No.: FLEX-001  
USSN: 10/613,761

### REMARKS

#### FORMAL MATTERS:

Claims 1-62 were pending. Of those, claims 1-4, 6-13, 17, 20, 24, 27, 28, 46-49, 51-53 and 55-57 were examined and rejected, and claims 5, 14-16, 18, 19, 21-23, 25, 26, 29-44, 50, 54 and 58-62 were previously withdrawn.

By this Amendment, claims 1 and 45 have been amended and claim 63 has been added. Support for these amendments is found throughout the specification and in the original claims.

Claims 1-63 are pending after entry of the amendments set forth herein, with claims 5, 14-16, 18, 19, 21-23, 25, 26, 29-44, 50, 54 and 58-62 being withdrawn.

#### DOUBLE PATENTING

Claims 1, 2, 27, 28 and 45 are provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 16 and 17 of copending U.S. Patent Application Serial No. 10/884,015. As this rejection is provisional, Applicants wish to wait upon allowance of claims in either the present application or the '015 application before submitting a Terminal Disclaimer.

#### REJECTIONS UNDER §112, ¶2

Claims 1-4, 6-13, 17, 20, 24, 27, 28, 45-49 and 51-56 were rejected under 35 U.S.C. §112, ¶2, as being indefinite with respect to phrase "interior plane".

Independent claims 1 and 45 have been amended to replace this phrase with alternate language which the Applicants believe meets the requirements of 35 U.S.C. §112.

#### REJECTIONS UNDER §102

Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by Mahmoodi (WO 98/18411).

Claim 1 is directed to an implantable device for repairing a cardiac valve where the device comprises a ring for attachment to the valve annulus, the ring defining a plane, and a restraining structure associated with the ring and extending inwardly or the ring and generally within the plane defined by the ring for restraining

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abnormal motion of at least a portion of one valve leaflet. Applicants are claiming two structures: (1) a ring and (2) a restraining structure.

On the contrary, Mahmoodi discloses a device which consists exclusively of a "ring", which ring is defined by hoops 10 and 12 and struts 14 and 16. No other structures are disclosed, nor do any of these specified four components of Mahmoodi's ring extend inwardly of the ring. Accordingly, Mahmoodi does not anticipate the subject matter of claim 1.

Claims 1-3, 6-12, 27, 45-49 and 53 were rejected under 35 U.S.C. §102(b) as being anticipated by Gabbay (WO 01/89418).

Independent claims 1 and 45 require the restraining structure/member to extend inwardly of the ring and generally within the plane defined by the ring.

In the Office Action, it appears that the buttress (20) of Gabbay's device is being characterized as corresponding to the claimed restraining structure (claims 1-3, 6-12, 27) and the claimed "at least one member" (claims 45-49, 53), and further characterized as extending over the interior of the ring. Applicants agree with the Examiner that Gabbay's buttress extends over the interior of the ring; however, what the buttress does not do is extend within the plane defined by the ring. On page 6, lines 8-9 of Gabbay, the buttress is described as extending "generally axially from and radially outwardly relative to the outflow side 18 of the base portion 12." No portion of Gabbay's buttress extends within the plane defined by the ring, as is clearly illustrated in Gabbay's drawings, for example Figs. 4 and 8. There is an important reason for Gabbay's buttress to extend outwardly away from the ring's plane. As illustrated in Figs. 11 and 12 of Gabbay, when implanted within the mitral valve, the buttress 20 extends into the left ventricle 306, i.e., outside the plane defined by base portion 12, to function as a prosthetic posterior leaflet. If the buttress were within the ring's plane, it would not be able to function as a prosthetic leaflet. Accordingly, Gabbay does not anticipate the subject matter of claims 1-3, 6-12, 27, 45-49 and 53.

Claims 1-4, 9-13, 17, 20, 24, 27, 28, 45, 46, 51, 52 and 57 were rejected under 35 U.S.C. §102(b) as being anticipated by Bessler et al. (WO 01/47438).

All of the claims are directed to an implantable device – meaning that the entirety of the device is implantable, i.e., the ring as well as the claimed restraining structure (claims 1-4, 9-13, 20, 24, 27, 28), the claimed "at least one member" (claims 45, 46, 51, 52) and the claimed plurality of cross-members (claim 57).

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In the Office Action, it appears that Bessler's template 206 is being characterized as corresponding to the claimed restraining structure of claims 1-4, 9-13, 20, 24, 27, 28, the claimed "at least one member" of claims 45, 46, 51, 52 and the claimed plurality of cross-members of claim 57. Bessler et al. discloses the use of fairly conventional implantable annuloplasty rings, such as those disclosed in Figs. 9A and 9B. Bessler et al. also disclose a method of implanting those annuloplasty rings which employs a tool to insert and position the ring with a valve annulus. The tool includes a template 206 having a lanyard 208 and a handle 210 attached to the template (see page 14, lines 9 and 10). As clearly specified in Bessler et al, the ring 200 is removably secured to the template (page 14, lines 11, 12, 22 and 23) so as to facilitate positioning the ring within the valve. The tool and template are subsequently detached from the ring (page 14, lines 20 and 21) after the ring is seated within the heart valve and prior to closing the incision. The template does not remain with the ring nor is it in any way configured to be implanted within the heart. As such, the template is not part of an implantable device. Accordingly, Bessler et al. do not anticipate the subject matter of claims 1-4, 9-13, 17, 20, 24, 27, 28, 45, 46, 51, 52 and 57.

#### REJECTIONS UNDER §103(A)

Claims 55 and 56 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bessler et al. in view of Solem et al. (6,210,432). For at least the reasons stated above traversing the rejection of claim 45 as being anticipated by Bessler et al., and because Solem et al. does not make up for the deficiencies of Bessler et al., claims 55 and 56, which are dependent upon claim 45, are not unpatentable over Bessler et al. in view of Solem et al.

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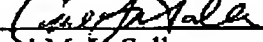
**CONCLUSION**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number FLEX-001.

Respectfully submitted,  
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Date: August 22, 2005

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